

Remarks

This Amendment is submitted in response to the office action mailed March 7, 2006, in connection with the above-identified application (hereinafter the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on June 7, 2006. Submitted herewith is a petition for a one-month extension of time extending the due date to July 7, 2006.

Claims 1, 4 through 6, 32 through 37 are currently pending. Applicants respectfully request that Claims 4 through 6, and 33 be cancelled without prejudice. Applicants also respectfully request entry of the amendment to Claim 1. Thus, claims 1, 32 through 37 are pending. No new matter is introduced by the amendment to Claim 1.

Rejection under 35 U.S.C. § 112

Claims 1, 4-6 and 32-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 1 recites "active agent having low water solubility encapsulated in nanoparticles comprising solubilizing agent." Applicants have amended the claim to replace the term "solubilizing agent" with "pharmaceutically acceptable polymer" Additionally, Claim 33 which refers to "polyvinyl alcohol has a degree of hydrolysis greater than 70%" has been cancelled.

Thus, Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 4-6 and 32-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Preparation of aqueous polymeric nanodispersions by a reversible salting-out process: influence of process parameters on particle size* to Allémann et al. (hereinafter "Allémann") or record by itself or in combination with U.S. Patent No. 4,343,789 to Kawata (hereinafter "Kawata"), U.S. Patent No. 5,482,706 to Igari (hereinafter "Igari") or U.S. Patent No. 4,895,725 to Kantor (hereinafter "Kantor").

First, *Allémann* by itself does not render the amended claims obvious. All the claim limitations need to be taught by the reference in order to establish obviousness. Claim 1 has been amended to remove reference to copolymers consisting of (a) methacrylic acid or acrylic acid and (b) methyl or ethyl esters of acrylic or methacrylic acid monomers (i.e. polymers that are commercially available under the trademark EUDRAGIT). *Allémann* does not disclose or teach the remaining polymers claimed in Claim 1, i.e., polyvinyl acetate phthalate (PVAP),

hydroxypropyl methyl cellulose acetate succinate (HPMCAS), hydroxypropyl methyl cellulose phthalate (HPMCP), cellulose acetate phthalate (CAP) and cellulose acetate trimellitate (CAT).

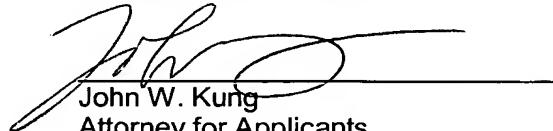
The Office Action also cites that *Allémann* and *Kawata* can be combined to render the present invention obvious. Once again, the Applicants submit that *Allémann* and *Kawata* both concern different areas of pharmaceutics. First *Allémann* focuses on developing polymeric nanodispersions for injectable dosage forms. The resulting dosage forms are aqueous suspensions, i.e. in a liquid state. In complete contrast, *Kawata* discloses sustained release oral solid dosage forms. Specifically, the pharmaceutical compositions of *Kawata* can be used in formulations such as powders, granules, tablets, pills and capsules (see 3:16). Nowhere does *Kawata* mention suspensions or the like. This distinction between *Allémann* and *Kawata* is critical as it calls into question whether there is a motivation to combine the art. Applicants respectfully submit that there is not any motivation to combine *Kawata* with *Allémann* or any of the art cited in the Office Action. One reference teaches parenteral dosage forms whereas the other teaches oral dosage forms. One reference teaches solid dosage forms whereas the other teaches nanoparticles suspended in an aqueous vehicle. Without any motivation to combine, there is no *prima facie* case of obviousness.

Allémann, according to the Office Action, can also be combined with *Igari* or *Kantor*. As discussed above, *Allémann* fails to teach or disclose the polymers of Claim 1. Neither *Igari* nor *Kantor* disclose the polymers of Claim 1, thus the use of *Igari* and/or *Kantor* does not cure the deficiencies in *Allémann*, i.e., not teaching each and every limitation of Claim 1. It is for these reasons that a *prima facie* case of obviousness has not been made. Furthermore, *Igari* and *Kantor* teach dosage forms not similar to the injectable dosage form of *Allémann*, and thus there is no motivation to combine the art, and this further weakens the case for obviousness.

Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Thus, in view of the foregoing arguments, Applicants respectfully request reconsideration of the present application. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Respectfully submitted,



John W. Kung
Attorney for Applicants
Reg. No. 44,199

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7877

Date: June 15, 2006